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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/552,649

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EXAMINER

JUNG, UNSU

ART UNIT

PAPER NUMBER

1641

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/552,649	Applicant(s) GRANELI ET AL.	
	Examiner UNSU JUNG	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 July 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-13,15,17-22,33-37,39 and 41-65 is/are pending in the application.
- 4a) Of the above claim(s) 6,7,9-13,15,17-22,33-37,39 and 41-62 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5,8 and 63-65 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 October 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 9, 2010 has been entered.

The submission included amendments to claims 1, 5, 8, 20, and 44, cancellation of claims 4, 16, 38, and addition of new claims 63-65.

Status of Claims

2. Claims 1-3, 5-13, 15, 17-22, 33-37, 39, and 41-65 are pending, claims 6, 7, 9-13, 15, 17-22, 33-37, 39, and 41-62 have been withdrawn from consideration, and claims 1-3, 5, 8, and 63-65 are currently under consideration for patentability under 37 CFR 1.104.

Priority

3. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. The instant application is a national phase under 35 U.S.C. 371 of PCT International Application No.

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PCT/SE2004/000555, filed on April 7, 2004 and claims priority under 35 U.S.C. §119 to Application Serial No. 60/461,197 filed April 9, 2003.

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy of Sweden 0301038-6 has been filed on April 7, 2003 in the instant application.

Oath/Declaration

4. The objection of the oath/declaration has been withdrawn in view of the new oath/declaration submitted in the reply filed on July 9, 2010.

Objections Withdrawn

5. The objection of claim 5 has been withdrawn in view of the amended claim 5 in the reply filed on July 9, 2010.

Rejections Withdrawn

6. The rejection of claims 1-5 and 8 under 35 U.S.C. 102(a) and 102(e) as being anticipated by Bredehorst et al. (WO 02/081739 A2, published Oct. 17, 2002 and filed Apr. 9, 2001) has been withdrawn in view of the amended independent claim 1 in the reply filed on July 9, 2010.

New Grounds of Rejections

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1 and 65 are rejected under 35 U.S.C. 102(b) as being anticipated by Patolsky et al. (*J. Am. Chem. Soc.*, 2001, Vol. 123, pp5194-5205) (hereinafter “Patolsky”).

Patolsky anticipates instant claims by teaching electronic transduction of DNA sensing process on surfaces (see entire document). The method for the amplified detection of an analyte DNA is depicted in Scheme 1 (p5197). In Scheme 1A, double stranded assembly is formed on the surface. A liposome with an oligonucleotide (3) interacts directed with double stranded assembly is formed on the surface resulting in immobilized liposome with biologically active oligonucleotides (p5196, *Results and Discussion*).

With respect to claim 65, Patolsky teaches oligonucleotide as the biologically active compound (p5196, *Results and Discussion* and Scheme 1A).

New Grounds of Rejections

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 1, 8, and 63-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hamalainen et al. (U.S. PG Pub. No. US 2002/0019019 A1, Feb. 14, 2002) (hereinafter "Hamalainen") in view of Keinanen et al. (U.S. Patent No. 6,235,535 B1, May 22, 2001) (hereinafter "Keinanen") and Mirkin et al. (U.S. Patent No. 6,361,944 B1, Mar. 26, 2002) (hereinafter "Mirkin").

Hamalainen teaches a biosensor with a sensor surface comprising a hydrogel matrix coating coupled to a top surface of the sensor surface, wherein the hydrogel matrix coating has plurality of functional groups. At least two different liposomes (vesicles) are bonded to the plurality of functional groups at discrete and noncontiguous locations on the hydrogel matrix coating of the sensor surface.

However, Hamalainen fails to teach that the vesicles are immobilized on the surface via hybridization of linker oligonucleotides and that vesicles comprise biologically active compound.

With respect to claims 1 and 63-65, Keinanen teaches that lipid bilayers are known to be structures that are spontaneously formed by phospholipids and some other polar lipids in water solution (see entire document, particularly column 2, lines 4-30). Vesicular closed lipid bilayer structures or liposomes can be prepared (column 2, lines 4-30). A lipid membrane can be regarded as a two-dimensional liquid, in which the lipid molecules and the other molecules like proteins that are associated with it (natural membrane structures such as cell membranes) or have been attached on it, do move relatively freely on the plane of the membrane (lateral diffusion, column 2, lines 4-30).

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There are applications which are based on the function of molecules which participate in specific binding and recognition reactions and are attached on lipid membranes (column 2, lines 4-30). This kind of functional lipid membranes have substantial potential as e.g. recognition surfaces in biosensors (column 2, lines 4-30).

With respect to claims 1 and 8, Mirkin teaches a method of immobilizing and assembling particle structures to a solid surface (see entire document). Immobilization method involves specific hybridization interaction between oligonucleotides (column 5, lines 1-26). This type of assembling method allows systematic control for making designed and well defined structures (column 1, lines 49-58).

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to employ liposomes (vesicles) associated with membrane proteins in the method of Hamalainen since Keinanen teaches that such liposomal structure can be used as recognition surfaces in biosensors. The advantage of using the liposomes as a recognition surfaces in biosensors provides the motivation to combine teachings of Hamalainen and Keinanen with a reasonable expectation of success.

Further, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to employ immobilization method of Mirkin, in which vesicles are immobilized on the surface via hybridization of linker oligonucleotides in the method of Hamalainen in view of Keinanen in order to make designed and well defined biosensor surface structures. The advantage of allowing systematic control for making designed and well defined biosensor surface structures provides the motivation to

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combine teachings of Hamalainen in view of Keinanen and Mirkin with a reasonable expectation of success.

13. Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hamalainen (U.S. PG Pub. No. US 2002/0019019 A1, Feb. 14, 2002) in view of Keinanen (U.S. Patent No. 6,235,535 B1, May 22, 2001) and Mirkin (U.S. Patent No. 6,361,944 B1, Mar. 26, 2002) as applied to claim 1 above, and further in view of Kataoka et al. (U.S. PG Pub. No. US 2005/0079195 A1, Apr. 14, 2005, filed Nov. 3, 2000) (hereinafter "Kataoka").

Hamalainen in view of Keinanen and Mirkin teaches a biologically functional surface immobilized structure as set forth above.

However, Hamalainen in view of Keinanen and Mirkin fails to teach that the vesicles are attached to other vesicles via binding vesicle-attached linkers, which are oligonucleotides and the binding of the vesicle-attached linkers are mediated through hybridization.

Kataoka teaches a coated support surface comprising multilayer micelles (vesicles/liposomes) on a support surface for use in biomedical application (see entire document, particularly p2, paragraph [0029] and Fig. 1).

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to employ the multilayer format of Kataoka in the structure of Hamalainen in view of Keinanen and Mirkin in order to provide a functional surface with greater surface area for biosensing application. The advantage of having

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increased functional surface area provides the motivation to combine teachings of Hamalainen in view of Keinanen and Mirkin and Kataoka with a reasonable expectation of success. One of ordinary skill in the art at the time of the invention would have been motivated to use assembling method of Mirkin, in which the particle structures are attached to each other via hybridization of oligonucleotides, for the reasons set forth above.

14. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hamalainen (U.S. PG Pub. No. US 2002/0019019 A1, Feb. 14, 2002) in view of Keinanen (U.S. Patent No. 6,235,535 B1, May 22, 2001) and Mirkin (U.S. Patent No. 6,361,944 B1, Mar. 26, 2002) as applied to claim 1 above, and further in view of Bredehorst et al. (WO 02/081739 A2, published Oct. 17, 2002 and filed Apr. 9, 2001) (hereinafter "Bredehorst").

Hamalainen in view of Keinanen and Mirkin teaches a biologically functional surface immobilized structure as set forth above.

However, Hamalainen in view of Keinanen and Mirkin is silent on teaching attachment method for the vesicle-attached linkers.

Bredehorst teaches linkers such as oligonucleotide can be attached to vesicles via a covalent bond using a functional group (see entire document, particularly p10, line 30-p11, line 10).

The rationale to support a conclusion that the claim would have been obvious is that all the claimed elements were known in the prior art and one skilled in the art could

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have combined the elements as claimed by known methods with no change in their respective functions, and the combination yielded nothing more than predictable results to one of ordinary skill in the art. *KSR International Co. v. Teleflex Inc.*, 550 U.S. at ___, 82 USPQ2d at 1395; *Sakraida v. AG Pro, Inc.*, 425 U.S. 273, 282, 189 USPQ 449, 453 (1976); *Anderson's-Black Rock, Inc. v. Pavement Salvage Co.*, 396 U.S. 57, 62-63, 163 USPQ 673, 675 (1969); *Great Atlantic & P. Tea Co. v. Supermarket Equipment Corp.*, 340 U.S. 147, 152, 87 USPQ 303, 306 (1950). “[I]t can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.” *KSR*, 550 U.S. at ___, 82 USPQ2d at 1396. Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to a known oligonucleotide immobilization method of Bredehorst in the structure of Hamalainen in view of Keinanen and Mirkin since immobilization techniques are well known in the arts. One skilled in the art would have combined the oligonucleotide immobilization method as claimed by known methods with no respective functions and the combination would yield nothing more than predictable result of obtaining vesicles having attached oligonucleotides.

Double Patenting

15. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140

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F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

16. Claims 1-5, 8, and 63-65 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-22 of copending Application No. 10/590,877. Although the conflicting claims are not identical, they are not patentably distinct from each other because each recites a biologically functional surface immobilized multilayer structure comprising a plurality of vesicles sufficiently spaced apart from the surface. The vesicles are directly attached to the structure by surface-immobilized linkers with vesicle-attached linkers and optionally by vesicle-attached linkers to another vesicle. The vesicles comprise the biologically active compounds, which provide the structure with its biological functionality. Therefore, the claims of the copending Application anticipate the claims of instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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Response to Arguments

17. Applicant's arguments with respect to claims 1-3, 5, 8, and 63-65 have been considered but are moot in view of the new ground(s) of rejection.

18. Since the prior art fulfills all the limitations currently recited in the claims, the invention as currently recited would read upon the prior art.

Conclusion

19. No claim is allowed.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to UNSU JUNG whose telephone number is (571)272-8506. The examiner can normally be reached on M-F: 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on 571-272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Unsu Jung/
Unsu Jung
Primary Examiner
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